IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE STATE OF MICHIGAN, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE STATE OF WISCONSIN, THE COMMONWEALTH OF MASSACHUSETTS, THE COMMONWEALTH OF VIRGINIA, THE DISTRICT OF COLUMBIA, THE CITY OF CHICAGO, THE STATE OF CONNECTICUT, THE STATE OF COLORADO, THE STATE OF MARYLAND, THE STATE OF IOWA, and THE STATE WASHINGTON ex rel. CHARLES STRUNCK and LISA PRATTA, and Lisa Pratta individually vs. Mallinckrodt ARD, Inc (formerly known as Questcor Pharmaceuticals, Inc., a California corporation), and Mallinckrodt, plc, an Irish public limited company Defendants.	Docket No. 12-175 (BMS) FILED UNDER SEAL FOURTH AMENDED QUI TAM COMPLAINT

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RELATOR'S FOURTH AMENDED QUI TAM COMPLAINT

I. NARRATIVE SUMMARY

1. Plaintiffs/Relators hereby file this Fourth Amended Complaint[1] (Complaint) pursuant to Section 31 U.S.C. Title 3729 and 3730, under which a civil action may be brought for violations of 31 U.S.C. Section 3729 regarding false claims on behalf of the United States Government and the various States and municipalities listed herein under their own False Claims Act. This is an action to recover damages and civil penalties on behalf of the United States and various States or municipalities listed herein arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendant Mallinckrodt ARD, Inc. (formerly known as Questcor Pharmaceuticals, Inc[2].), (Questcor) "a subsidiary of Mallinckrodt, plc[3] (Mallinckrodt). Questcor and Mallinckrodt are both referred to collectively as "Questcor" or ("Defendant(s)") and/or their agents,

[1] The Original Complaint was filed on January 17, 2012 and served on the United States on January 31, 2012. The First Amended Complaint was filed on or about August 8, 2013 and was also timely served on the United States. A Motion for leave to file the Second Amended Complaint was filed and granted on or about September 7, 2012. The Second Amended Complaint was timely served on the United States and the States named therein. A motion to file a Third Amended Complaint was granted and filed July 1, 2014 to include additional States which were inadvertently omitted in the Second Amended Complaint, being Washington, Maryland, Connecticut, Iowa and Maryland.

[2] The corporate name change was filed with the California Department of State on July 27, 2015 (Document ID# A0772903)

[3] On August 14, 2014, pursuant to the Agreement and Plan of Merger (the "Merger Agreement"), dated as of April 5, 2014, among Questcor Pharmaceuticals, Inc. ("Questcor"), Mallinckrodt, plc, an Irish public limited company ("Mallinckrodt") and Quincy Merger Sub, Inc. ("Merger Sub"), Merger Sub merged with and into Questcor, with Questcor being the surviving entity (the "Merger"). As a result of the Merger, Questcor became a wholly owned indirect subsidiary of Mallinckrodt.

employees or co-conspirators under the False Claims Act. Relator Pratta is also bringing individual causes of actions under the New Jersey Conscientious Employee Protection Act N. J. Stat. Ann. § 34:19-1 et. seq. ("CEPA") and New Jersey Law Against Discrimination N. J. Stat. Ann. N.J.S.A. 10:5-12 ("LAD")

2. Questcor manufactured, marketed and sold drugs for medicinal purposes, and its only FDA-approved product was H.P. Acthar Gel (repository corticotrophin injection). Acthar is a "specialty pharmaceutical. " It is neither sold in retail pharmacies, nor distributed through wholesalers to retail pharmacies. Instead, it is distributed through "specialty pharmacies." Distinguishing features of specialty pharmaceuticals like Acthar, beyond their high prices, is their alleged important therapeutic effects. Since the Merger Defendants have collectively continued to manufacture, market and sell H.P. Acthar Gel

3. Since at least 2007, Questcor has intentionally engaged in an illegal scheme to increase its sales and profits by engaging in the following illegal and fraudulent activities:

(i) in violation of the Anti-Kickback Statute[4] ("AKS") using valuable incentives, rewards and other forms of remuneration to induce healthcare providers to promote and prescribe H.P. Acthar Gel, in lieu of less-expensive therapies that are equally or more effective, for use by Government Health Care Program beneficiaries;

(ii) systematically promoting and marketing H.P. Acthar Gel for

[4] The Medicare, Medicaid and Anti-Kickback Act ("AKA") 42 U.S.C. §1320a-7b(b)

unapproved, off label uses with regard to the dosing and administration of the drug using means and methods that are false, misleading and deceptive, and

(iii) systematically promoting and marketing H.P. Acthar using means and methods that are false, misleading and deceptive for unapproved off label uses to patients who have the progressive form of multiple sclerosis (MS) through a practice known as "pulse' therapy," even though it is only indicated for acute exacerbations or relapses. These types of MS patients are not indicated for H. P. Acthar Gel because they are not having acute relapses. Pulse therapy is a term used for monthly use or infusion of a drug on a prophylactic type basis. Even though Acthar is not indicated for this use, Questcor and their sales reps have been promoting this use to physicians and successfully getting it approved through a series of deceptive and misleading practices as described herein.

(iv) causing hundreds or thousands of false claims for reimbursement of H.P. Acthar Gel to be submitted to, and paid by, federal healthcare programs.

4. Defendant's conduct has cheated the federal government out of millions of dollars that should not have been paid, thereby enriching Defendant and subjecting patients to unapproved, unsafe and potentially ineffective uses of H.P. Acthar Gel.

5. These deceptive, false, and misleading methods included, inter alia, Defendant knowingly (i) disregarded federal laws and Food and Drug Administration ("FDA") regulations relating to off-label marketing and promotion; (ii) misrepresenting in it's promotion and marketing evidence concerning the efficacy

and safety of H.P. Acthar Gel; (iii) failing to disclose and submit to FDA all of its promotion, advertisements and marketing materials as required (iv) promoted H.P. Acthar Gel for uses that were neither effective nor safe; (v) utilized improper, false and misleading comparative marketing tactics, including unsubstantiated superiority claims; and (vi) improperly compensating, including giving free vials of H.P. Achtar Gel as an inducement, to healthcare professionals to induce them to promote and prescribe H.P. Acthar Gel. These illegal practices caused the submission of false claims. In so doing, Defendant has endeavored to undermine an important patient protection regulatory scheme that was developed over the course of almost fifty years.

6. The purpose of this Fourth Amended Qui Tam Complaint (herein "Complaint") is to (i) include additional evidence and facts that have been previously provided to the Government through voluntary supplemental disclosures since before and the filing of the Third Amended Complaint, (ii) reflect that the illegal practices that Questcor had been engaging in since 2007 have knowingly been continued since the merger and acquisition of Questcor by Mallinckrodt, and (iii) name and identify the Jane Doe relator, and include an individual causes of action for her (Lisa Pratta) under the New Jersey Conscientious Employee Protection Act N. J. Stat. Ann. § 34:19-1 et. seq. ("CEPA") and the New Jersey Law Against Discrimination N. J. Stat. Ann. N.J.S.A. 10:5-12 ("LAD").

II. PARTIES

A. Plaintiffs/Relators Charles W. Strunck and Lisa Pratta

7. Plaintiff/Relator Charles W. Strunck ("Relator Strunck") is a resident of the State of New York. He received a Bachelor of Science degree from Ramapo College of New Jersey in 1992. Relator Strunck was employed by Questcor from September 2010 until August 4, 2011 as a Multiple Sclerosis (MS) Sales Specialist with responsibility for sales in the States of New York and Connecticut.

8. Relator Strunck held the title of MS Sales Specialist throughout his tenure with Questcor. As such, his primary assigned role was to call on health care providers, including MS Centers and community-based neurologists, within his assigned region, and to encourage them to prescribe his H.P. Acthar Gel for their patients. Relator Strunck's compensation package was calculated as base compensation plus a bonus calculated based on total sales. In addition, Questcor from time to time would run "Special Incentive Plans" under which sales specialists could earn additional amounts based on sales volume.

9. Questcor terminated Relator Strunck's employment when injuries he suffered in a work-related motor vehicle accident (in which the other driver was at fault) ostensibly had a negative impact on his ability to do his job. Relator Strunck has initiated a worker's compensation claim as a result of the incident.

10. Relator Lisa Pratta (Relator Pratta) was an Achtar neurology specialists

with Questcor and thereafter Mallinckrodt from September 2010 until June 2017.

11. Relator Pratta's compensation package was calculated as base compensation plus a bonus calculated based on total sales. In addition, Questcor from time to time would run "Special Incentive Plans" under which sales specialists could earn additional amounts based on sales volume.

12. Relator Pratta promoted Acthar Gel (repository corticotropin injection) to Neurologists and Neuro-Ophthalmologists for MS relapses, optic neuritis., and neuromuscular indications such as dermatomyositis and polymyositis.

13. During her employment, Relator Pratta conducted Health Care Provider and patient programs, worked closely with the MS society and the MSAA and developed many Key Opinion Leader speakers.

14. Relator Pratta's employment was terminated as a result of her complaints and objections to supervisory personnel regarding a myriad of compliance issues as is more particularly described herein.

15. Relator Strunck and Relator Pratta are original sources of the Fraudulent Marketing Scheme allegations in this Complaint. The allegations in the Fraudulent Marketing Scheme are not based upon publicly disclosed information. Prior to filing this Complaint, Relators have provided the United States with Disclosure Statements as part of Relator's obligation to provide the government with material information prior to filing a Complaint in accordance with 31 U.S.C. § 3730(b)(2).

B. Defendant Questcor Pharmaceuticals, Inc.

16. Defendant Questcor Pharmaceuticals, Inc. is a California corporation headquartered in Anaheim, California and traded on the NASDAQ Exchange (Ticker Symbol: QCOR). It is a specialty pharmaceutical company focused on treating central nervous system disorders. On August 14, 2014, Questcor Pharmaceuticals, Inc. became a wholly owned indirect subsidiary of Mallinckrodt plc, an Irish public limited company ("Mallinckrodt"). Questcor changed it's name to Mallinckrodt ARD, Inc (formerly known as Questcor Pharmaceuticals, Inc., a California corporation.

17. Questcor, in or about January 2012, employed approximately 150 full-time employees, including a recently expanded Multiple Sclerosis ("MS") sales force of 77 sales representatives and 15 sale & managers. According to Questcor's 2010 Annual Report, the expansion of its MS sales force *"continues to allow [Questcor] to build upon positive growth trends in prescriptions of Acthar for the treatment of exacerbations associated with MS."* By 2014 the neurology sales force had grown to 87 sales representatives.

18. As of 2012, Questcor's National Sales Directors are Ed Hardin (East) and Doug Harmon (West), and they report to Eldon Mayer, who is the company's Vice President for Commercial Operations. The company's MS sales force is divided among 13 regions, each of which has its own Regional Manager. Relator Strunck was assigned to the Northeast Region and his Regional Manager was Ken Miller. Relator Pratta was also assigned to the Northeast Region.

19. Questcor also employs a team of medical science liaison ("MSLs") who report to the Director of Medical Science Liaisons, Nikki Mutschler. As of November 2010, Questcor employed ten MSLs. Sagar Shah is the MSL who was assigned to work with Relator Strunck.

20. At all times relevant to this Complaint, Defendant required its neurology sales specialists to promote and sell H.P. Acthar Gel to healthcare professionals throughout the United States.

21. Defendant expressly tied sales specialist compensation to sales growth, and it incentivized each sales specialist to increase sales growth irrespective of the rules against off label marketing. Indeed, the company's bonus structure - which paid hefty bonuses each month based on the number of prescriptions shipped - was designed to promote a "sell at all cost" mentality within the sales force.

22. Sales bonuses at Questcor are among the highest in the industry. In Q2 2011, the highest bonus paid to a sales specialist was $124,000 (Nick Brunetti, Denver), which included $75,000 in one month alone. Another sales specialist, Jason Ambrose, earned a $110,000 bonus during the same quarter, including $80,000 in one month alone. Questcor provides each sales specialist with a daily report tracking the productivity of all specialists in order to motivate them. This practice continued after the merger with Mallinckrodt.

23. Questcor required its sales specialists to promote and sell H.P. Acthar Gel to healthcare professionals throughout the United States. Questcor's sales

organization is relatively flat, ensuring that senior executives of the company are fully aware of the company's marketing strategies and results on a "real time" basis. In 2010, Questcor's net sales were approximately $115 million, reflecting significant year-over-year growth of approximately thirty percent.

24. Questcor reported to the U.S. Securities and Exchange Commission that net sales for Q2 2011 had increased approximately 62% over the same period in 2010, and that earnings per share had increased approximately 50% over the same period in 2010.

25. Substantially all of Questcor's sales are sales of H.P. Acthar Gel, and thus it is the linchpin of the company's financial success. Questcor stated in its Ql 2011 earnings call that net sales in the multiple sclerosis (MS) market were (then) approximately 60% of total net sales of the drug. The company repeatedly has told analysts and investors that it has experienced significant growth in scripts and revenues, and that it projects significant further growth in scripts and revenues, based largely on prescriptions for MS patients. Total net sales were $798.9 million for the year ended December 31, 2013 as compared to $509.3 million and $218.2 million for the years ended December 31, 2012 and 2011, respectively. Over 95% of net sales in each of these years were from H.P. Acthar Gel.

26. As described more fully herein, Questcor manufactures markets and sells H.P, Acthar Gel throughout the United States. During the relevant period,

Questcor marketed and sold substantial quantities of H.P. Acthar Gel in the United States.

27. H.P. Acthar Gel is paid or reimbursed by various Governmental Health Care Programs as set and described herein. According to Questcor's 2010 Annual Report, approximately 25% of the company's MS sales are to Medicare insureds. As a result of Questcor's actions described herein, the Government Health Care Programs have suffered financial harm.

C. The United States and State Plaintiffs

28. The United States of America is a real party in interest pursuant to the FCA, and specifically on behalf of several United States' agencies: the Department of Health and Human Services ("HHS"); its Centers for Medicare & Medicaid Services ("CMS"), as CMS administers the Medicare programs and the Food and Drug Administration ("FDA") which the Defendants' unlawful and fraudulent actions harmed.

29. The United States of America is a real party in interest pursuant to the FCA, and specifically on behalf of two United States' agencies: the Department of Health and Human Services ("HHS"), and particularly its Centers for Medicare & Medicaid Services ("CMS"), formerly the Health Care Financing Administration, as CMS administers the Medicare and Medicaid programs which the Defendants' unlawful and fraudulent actions harmed.

30. The States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas and Wisconsin, together with the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago are real parties in interest pursuant to each of their State FCAs, listed above, on behalf of each of their Medicaid agencies, which administer and fund each of said governmental entity's portion of Medicaid expenditures, as further described below, and which Defendants' unlawful and fraudulent actions harmed.

III. JURISDICTION

31. This action arises under the FCA, 31 U.S.C. §§3729 et seq., and the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§1331 and 1345.

IV. VENUE

32. Venue in this district is proper pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §1391(b) and ©) since one or more of the Defendants transact business in this district and/or one or more of the acts at issue occurred in this district.

V. SUMMARY OF DEFENDANT'S ILLEGAL CONDUCT

A. The Purpose of The Fraudulent Marketing Scheme

33. It was the intentional plan and purpose of Questcor's scheme to illegally market H.P. Acthar Gel, beginning at least as early as 2007 and continuing to the

present as a subsidiary of Mallinckrodt, in order to increase sales of H.P. Acthar Gel by (i) providing valuable remunerations to induce and encourage physicians to promote and prescribe the drug for on- and off label uses; (ii) illegally promoting the drug (to both healthcare providers and patients), using false, deceptive and misleading methods and means, that are beyond the limit of its FDA approval with respect to the dosage and administration of the drug, causing the submission of false claims to the Government Health Care Programs and (iii) systematically promoting and marketing H.P. Acthar using means and methods that are false, misleading and deceptive for unapproved off label uses to patients who have the progressive form of MS through a practice known as "pulse" therapy, even though it is only indicated for acute exacerbations or relapses which caused the submission of false claims to the Government Health Care Programs.

34. Questcor intended that this scheme would cause greater quantities of H.P. Acthar Gel to be dispensed, including to Government Health Care Program beneficiaries, than otherwise would have been the case. Questcor intended that this would cause a higher dollar volume of reimbursements to be paid by Government Health Care Programs for the use of H.P. Acthar Gel than otherwise would have been the case, thereby enriching themselves. Indeed, one component of the scheme was an elaborate plan by Questcor to provide free, and often improper or fraudulent guidance and assistance to physicians to help them overcome barriers to reimbursement imposed by Government Health Care Programs. The underlying

purpose of the scheme was to maximize profits. These practices continued after the merger with Mallinckrodt.

35. Questcor's scheme was knowingly designed, at least in part, to enable it to sell H.P. Acthar Gel against a generic, substantially less expensive, steroid called Solu-Medrol (methylprednisolone sodium) that requires a shorter course of treatment for the treatment of exacerbations of MS than does H.P. Acthar Gel. These practices continued after the merger with Mallinckrodt.

36. The FDA-approved label[5] indicates a dosage and administration of a two to three week course of treatment with H.P. Acthar Gel, which in 2012 could cost as much as $150,000 per patient (assuming an 80-120 Unit daily dose over 21 days). In contrast, the cost for the recommended four-dose regime of Solu-Medrol, (the primary competitor of H.P. Acthar Gel) is estimated to be only $11,182 for in-patients, and less than $800 for out-patients. *See Robson, L.S. et al., Cost Analysis of methylprednisolone treatment of multiple sclerosis patients, CAN. J. NEUROL. Sci., 1998 Aug; 25(3): 222-9.*. More importantly, Solu-Medrol, unlike H.P. Achtar Gel, can properly be dosed in a five day treatment according to its "label" and FDA Approval.

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[5] Copy of the FDA Approved label is attached hereto as Exhibit A. See Section "Dosage and Administration" which states that *"In the treatment of acute exacerbations of multiple sclerosis, daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks may be administered. It may be necessary to taper the dose."*

B. The Manner and Means of Executing The Scheme

37. Questcor intentionally employed a multi-tiered strategy to implement its Fraudulent Marketing Scheme. First, Questcor paid illegal kickbacks, in the form of bribes, free vials of H.P. Achtar, speaking and advisory fees, business consulting services, and other things of value, to physicians and their staff in order to induce them to promote and prescribe H.P. Acthar Gel for on- and off-label uses, and to reward those who already had done so.

38. Second, Questcor intentionally trained and utilized its sales force to employ false, deceptive and misleading information to probatively promote and sell H.P. Acthar Gel for indications and treatment regimens that are not approved by the U.S. Food and Drug Administration (FDA), as follows:

(A) first, as a dosage over five (5) days, instead of 2-3 weeks, so that it could compete with Solu-Medrol. In fact, Questcor concluded that the only way they could compete with Solu-Medrol was to off label market H.P. Achtar Gel with a "five day dosing" which is the "indication" that is part of the Solu-Medrol label. The off-label marketing scheme is directed to both physicians and MS patients.

(B) second, Questcor sales representatives are trained and encouraged to promote "pulse therapy" which means writing prescriptions for one (1) to three (3) vials to be used once a month. In order to enable this, sales representatives suggest that physicians need to diagnosis the patient with "active flare" or "acute flare" meaning that the patient is experiencing a "relapse," "attack" or "exacerbation."